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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,928	06/21/2007	Robert Charles Rees	42133-200847	2826

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EXAMINER	
HARRIS, ALANA M	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/592,928	REES ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 25-51 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 25-51 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 25, 41, 44, 45 and 47-49, drawn to a polypeptide comprising a sequence, ILLWQPIPV (PAP.135) also identified as SEQ ID NO: 1 and the vaccine comprising said polypeptide. Claims 25, 41, 44, 45 and 47-49 will be examined with this Group to the extent the polypeptide is SEQ ID NO: 1.

Group II, claim(s) 25, 41, 44, 45 and 47-49, drawn to drawn to a polypeptide comprising a sequence, CPRFQELESETLKSE (PAP.161) also identified as SEQ ID NO: 2 and the vaccine comprising said polypeptide. Claims 25, 41, 44, 45 and 47-49 will be examined with this Group to the extent the polypeptide is SEQ ID NO: 2.

Group III, claim(s) 26-28, 42, 43, 46 and 50, drawn to an isolated mammalian nucleic acid molecule which encodes PAP.135 also identified as SEQ ID NO: 1. Claims 26-28, 42, 43, 46 and 50 will be examined with this Group to the extent the nucleic acid encodes SEQ ID NO: 1.

Group IV, claim(s) 26-28, 42, 46 and 50, drawn to an isolated mammalian nucleic acid molecule which encodes PAP.161 also identified as SEQ ID NO: 2. Claims 26-28, 42, 43, 46 and 50 will be examined with this Group to the extent the nucleic acid encodes SEQ ID NO: 2.

Group V, claim(s) 29 and 51, drawn to a monoclonal antibody, which binds to a polypeptide identified as PAP.135 (SEQ ID NO: 1). Claims 29 and 51 will be examined with this Group to the extent the monoclonal antibody is specific to SEQ ID NO: 1.

Group VI, claim(s) 29 and 51, drawn to a monoclonal antibody, which binds to a polypeptide identified as PAP.161 (SEQ ID NO: 2). Claims 29 and 51 will be examined with this Group to the extent the monoclonal antibody is specific to SEQ ID NO: 2.

Group VII, claim(s) 30, 31 and 35, drawn to a method of detecting or monitoring cancer comprising implementing a nucleic acid which encodes SEQ ID NO: 1 (PAP.135) a kit comprising said method. Claims 30, 31 and 35 will be examined with the instant Group to the extent the method reads on a nucleic acid assay utilizing SEQ ID NO: 1.

Group VIII, claim(s) 30, 31 and 35, drawn to a method of detecting or monitoring cancer comprising implementing a nucleic acid which encodes SEQ ID NO: 2 (PAP.161) and a kit comprising said method. Claims 30, 31 and 35 will be examined with the instant Group to the extent the method reads on a nucleic acid assay utilizing SEQ ID NO: 2.

Group IX, claim(s) 32-34, drawn to a method of detecting or monitoring cancer comprising determining elevated levels of a polypeptide, SEQ ID NO: 1 (PAP.135) a kit comprising said method. Claims 32-34 will be examined with the instant Group to the extent the method reads on a protein assay utilizing SEQ ID NO: 1.

Group X, claim(s) 32-34, drawn to a method of detecting or monitoring cancer comprising determining elevated levels of a polypeptide, SEQ ID NO: 2 (PAP.161) a kit comprising said method. Claims 32-34 will be examined with the instant Group to the extent the method reads on a protein assay utilizing SEQ ID NO: 2.

Group XI, claim(s) 36, 37 and 40, drawn to a method of treatment of cancer comprising administering a nucleic acid molecule that encodes SEQ ID NO: 1 (PAP.135). Claims 36, 37 and 40 will be examined with this Group to the extent the nucleic acid administered encodes SEQ ID NO: 1.

Group XII, claim(s) 36, 37 and 40, drawn to a method of treatment of cancer comprising administering a nucleic acid molecule that encodes SEQ ID NO: 2 (PAP.161). Claims 36, 37 and 40 will be examined with this Group to the extent the nucleic acid administered encodes SEQ ID NO: 1.

Group XIII, claim(s) 38, drawn to a method of treatment of cancer comprising administering a polypeptide, SEQ ID NO: 1 (PAP.135). Claim 38 will be examined with this Group to the extent the polypeptide administered is SEQ ID NO: 1.

Group XIV, claim(s) 38, drawn to a method of treatment of cancer comprising administering a polypeptide, SEQ ID NO: 2 (PAP.161). Claim 38 will be examined with this Group to the extent the polypeptide administered is SEQ ID NO: 2.

Group XV, claim(s) 39, drawn to a method of treatment of cancer comprising administering an antibody specific for SEQ ID NO: 1. Claim 39 will be examined with this Group to the extent the antibody administered binds SEQ ID NO: 1.

Group XVI, claim(s) 39, drawn to a method of treatment of cancer comprising administering an antibody specific for SEQ ID NO: 1. Claim 39 will be examined with this Group to the extent the antibody administered binds SEQ ID NO: 1.

2. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature recited in claim 1 is a polypeptide identified as ILLWQPIPV (PAP.135) and SEQ ID NO: 1. WO 94/020127 A1 (published 15 September 1994) teaches PAP.135, see sequence alignment and page 87. Therefore, the technical feature recited in claim 1 is not special. Accordingly, the groups are not so linked as to form a single general concept under PCT Rule 13.1.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5.

Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours, 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
31 October 2007